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10/594,584	09/27/2006	Bruno Mougin	129432	8064

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EXAMINER	
POHNERT, STEVEN C	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,584	MOUGIN ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-12* is/are pending in the application.

4a) Of the above claim(s) *2,7 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of 2/8/2008 in the reply filed on 2/8/2006 is acknowledged. The traversal is on the ground(s) that the matter of all the claims are sufficiently related. This is not found persuasive because this is a 371 of a PCT and lack of unity was demonstrated in the restriction requirement of 1/11/2008. Further the inhibitor of twist of group I can be used in a materially different method such as screening agents for treatment of disease. Further the kits of group 3, can be used to isolate nucleic acids with homology form a sample. Group 4 is different from group 2, as it is drawn to the use of an inhibitor from treatment and does not require detection of altered expression. Thus restriction is proper as unity has been broken and further the other inventions of the groups 1, 3, and 4 are distinct, and require separate search and examination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 7 and 12 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/8/2008.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. An example of an embedded hyperlink in the specification is page 14, line 22. Applicant is required to check the rest of the

disclosure and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 3-6, 8-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in the Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

<u>The nature of the invention and the breadth of the claims:</u>

"Any" cancer broadly encompasses breast, colon, neuroblastoma, gastric, etc.

"Any" subject broadly encompasses human, dog, cat, whale, mouse, etc. "any" subject further encompasses any humans of any ethnic group.

"Any" expression broadly encompasses increased, decreased or unchanged expression.

"Any" sample broadly encompasses hair, serum, blood, stool, urine, etc.

"Any" twist gene broadly encompasses any gene that broadly be encompassed by the recitation of twist, including any homologues, splice variant, mutants, insertions, deletions, translocations of any species. Twist gene broadly encompasses promoter, enhancer, all splice variants, etc of any species.

Claims 5 and 8 draw the invention to blood or tissue samples.

Claims 6 and 9-11 draws the claims to neuroblastoma or breast cancer.

The amount of direction or guidance and the Presence and absence of working examples.

The specification teaches, "12 stage 1/2 tumors, 4 stage 4s tumors and 7 stage 4 samples (2 tumor punctures, 1 biopsy, 4 massively invaded bone marrow punctures) were then distinguished"(see page 12, last paragraph). The specification teaches on top of page 13 patients with stage 1, 2 and 4s were described as patients with good prognosis. The specification teaches that analysis was carried out on 8 patients with poor prognosis and 15 patients with good prognosis. It is unclear where the 8^{th} patient with poor prognosis was obtained as the specification previously teaches 7 patients with stage 4 samples and all other samples were grouped into the good prognosis group.

The specification teaches RNA was isolated and hybridized to DNA chips for analysis (see page 13, lines 10-30). The specification teaches analysis of the arrays

demonstrated that there was a 10.8 fold over expression of the twist gene in neuroblastoma patients with good prognosis (see page 14, lines 23—25). The specification provides no guidance on what measures were used to normalize expression data.

The specification teaches 23 breast cancer samples were obtained and RNA was extracted (see page 15, lines 11-15). The specification teaches SBRI stage I tumors were classified as good prognosis and SBRII/III tumors were classified poor prognosis (see page 15, lines 6-10). The specification teaches that a 2.3 fold over expression of the twist gene was obtained in the poor prognosis group relative to the good prognosis group (see page 16, lines 3-7).

The specification in example 3 uses cell line data to demonstrate that over expression or twist is associated with N-myc (see page 19, lines 25-30). The specification further teaches that introduction of N-Myc or H-twist into wild type mouse embryonic fibroblasts (MEF) does not allow for the cells to be transformed. The specification thus teaches twist by itself is not able to transform cells and cause cancer. The specification further teaches that cells which were engineered to over express twist were able to undergo apoptosis if twist expression was inhibited by siRNA (see page 22, lines 22-24).

The specification in example 5 teaches that RNA interference of twist in breast cancer, neuroblastoma and melanoma cells allowed the cells to die by apoptosis. It is noted that the specification does not teach what stimulus was use to cause apoptosis nor presents data to demonstrate that the cells undergoing apoptosis were over

expressing twist or to what level. Further the specification does not teach to what level the knock down of twist was efficient or how long it lasted.

The state of prior art and the predictability or unpredictability of the art:

Maestro et al (Genes & Development (1999) volume 13, pages 2207-2217) teaches that twist is a potential oncogene that inhibits apoptosis. Maestro et al teaches the twist protein was not detectable in breast, colon, ovary and lung tissues, however, twist was seen to be increased in rhabdomyosarcomas (see page 2214, 1st column, top). Thus Maestro teaches that twist over expression is not predictably associated with breast cancer, thus contradicting the findings of the instant specification.

Rosivatz et al (Journal of Pathology (2002) volume 16, pages 1881-1891) teaches that twist is differentially expressed in gastric cancer (see abstract). Rosivatz et al teaches that twist expression is unregulated nearly two fold in gastric non-tumor samples (1a) while twist expression was decreased greater than 2 fold in gastric cancer tissue. Thus Rosivatz teaches that increased expression of twist is not predictably associated with cancer.

Yang et al (Cell (2004) volume 117, pages 927-939, available online 6/24/2004) teaches Twist gene expression is unregulated in breast cancer (see figure 7 and page 935, last paragraph 1st column to top of 2nd column).

Fackler et al (International Journal of Cancer (2003) volume 107, pages 970-975) teaches that the twist promoter was hypermethylated in breast cancer. Kass et al (trends in Genetics (1997) volume 13, pages 444-449) teaches that hypermethylation results in decreased transcription. Thus Fackler and Kass teach that decreased

expression of twist is associated with breast cancer, thus suggesting the increased expression taught by the specification is unpredictable.

Mehrotra et al (Proceedings/ Annual Meeting of the American Association for Cancer Research (2003) volume 44 page 432 R2203) teaches African American women have a higher mortality rate than Caucasian women and there is a difference in methylation of the twist gene promoter between the ethnic groups. Mehrotra thus teaches twist expression is unpredictable between ethnic groups, due to altered methylation.

Stasinopoulos et al (Proceeding American Association for Cancer Research (March 2002) page 611) that twist mRNA was detected from primary breast carcinoma samples and normal breast samples by RT-PCR and twist mRNA was always expressed. Stasinopoulos thus teaches that twist mRNA is expressed in all cells.

Sukumar et al (US 2003/0138783, published July 24, 2003) teaches a method of detecting breast cancer by examination of methylation of twist (see abstract). Sukumar teaches that twist hypermethylation was found in invasive lubular carcinoma cells and invasive ductal carcinoma cells (see paragraph 207). Thus Sukumar and Kass teach that decreased expression of twist is associated with breast cancer, thus suggesting the increased expression taught by the specification is unpredictable.

Twist1 GeneCard (GC07M01921, pages 1-13, 5/6/2008) teaches that twist gene expression varies across tissues and thus it would be unpredictable to associate increased expression in one tissue with a disease state in another tissue.

Vandesompele teaches, " Accurate normalization of gene expression levels is an

absolute prerequisite for reliable results, especially when the biological significance of subtle gene expression differences is studied" (see page 9, 2nd column, discussion) (Vandesompele et al (Genome Biology (2002) volume 3 , pages 1-11). Vandesompele teaches, " That the conventional use of a single gene normalization leads to relatively large errors in a significant portion of samples tested" (see abstract, results). Vandesompele teaches that ACTB (beta actin) appears to be the one of the worst genes for normalization and thus resulting in large normalization errors (see page 10, 1st paragraph). Vandesompele teaches at least 3 housekeeping genes are required for accurate normalization (see page 10, 1st column, 1st full paragraph). Vandesompele thus teaches that studies of gene expression using a single gene for normalization are unpredictable due to the large variation in the expression of the genes used for normalization.

The art of Cheung et al (Nature Genetics, 2003, volume 33, pages 422-425) teaches that there is natural variation in gene expression among different individuals. The reference teaches an assessment of natural variation of gene expression in lymphoblastoid cells in humans, and analyzes the variation of expression data among individuals and within individuals (replicates) p.422, last paragraph; Fig 1). The data indicates that, for example, expression of ACTG2 in 35 individuals varied by a factor of 17; and that in expression of the 40 genes with the highest variance ratios, the highest and lowest values differed by a factor of 2.4 or greater (Fig 3).

The unpredictability of correlating gene expression level to any phenotypic quality is taught in the prior art of Wu (Journal of Pathology, 2001, volume 195, pages 53-65).

Wu teaches that gene expression data must be interpreted in the context of other biological knowledge, involving various types of 'post genomics' informatics, including gene networks, gene pathways, and gene ontologies (p.53, left col.). The reference indicates that many factors may be influential to the outcome of data analysis, and teaches that expression data can be interpreted in many ways. The conclusions that can be drawn from a given set of data depend heavily on the particular choice of data analysis. Much of the data analysis depends on such low-level considerations as normalization and such basic assumptions as normality (p.63 - Discussion). The prior art of Newton et al (Journal of Computational Biology, 2001, volume 8, pages 37-52) further teaches the difficulty in applying gene expression results. Newton et al teaches that a basic statistical problem is determining when the measured differential expression is likely to reflect a real biological shift in gene expression, and replication of data is critical to validation (p.38, third full paragraph).

Brenner et al (Trends in Genetics (2001) volume 17, pages 414-418) teaches that, “Here, the ‘homology-implies-equivalency’ assumption is restricted to a subset of homologs that diverged in the most-recent common ancestor of the species sharing the homologs. This strategy is useful, of course. But it is likely to be far less general than is widely thought. Two species living in the same space, almost by axiom, cannot have identical strategies for survival. This, in turn, implies that two orthologous proteins might not contribute to fitness in exactly the same way in two species” (see page 414, 3rd column last full paragraph). Brenner specifically describes that although the leptin gene homologs have been found in mice and humans, their affect is different (see page 414,

3rd column last paragraph-3rd column page 415). Brenner specifically teaches that the leptin gene in mice plays a major role in obesity, but no such effect has been demonstrated in humans due perhaps to the different evolutionary forces. Brenner thus teaches that the activity and function of genes in different species is unpredictable.

The level of skill in the art:

The level of skill in the art is deemed to be high.

Quantity of experimentation necessary:

In order to practice the invention as claimed the artisan would have to determine if the expression of twist gene is predictably associated with diagnosis or prognosis of "any" cancer. Determining if twist gene expression is predictably associated with twist expression would require undue trial and error experimentation. The experimentation would be undue and unpredictable because Maestro et al contradicts the instant specification as he teaches that twist is not detectable in breast cancer. Thus Maestro suggests altered expression of twist may not be predicative of breast cancer. Fackler and Sukumar teach that the twist promoter is hypermethylated in breast cancer and thus suggesting that twist expression is decreased in breast cancer which again contradicts the teachings of the instant specification. Thus the combined teachings of Maestro, Fackler and Sukumar teach that increased expression of twist is not predictably associated with diagnosis or prognosis of breast cancer, as they teach decreased expression of twist due to hypermethylation.

Further there is unpredictability in the expression of twist gene between ethnic groups, as Mehrotra methylation is different in Caucasian and African Americans. Thus

it is unpredictable use expression of a gene for diagnosis when it is known to be differently regulated in different ethnic groups.

The experimentation would further be unpredictable and undue as Rosivatz teaches that different types of gastric cancer have increased or decreased expression of twist. Thus the skilled artisan would have to determine if increased or decreased expression of twist is indicative of diagnosis or prognosis of “any” cancer. Further in view of Maestro’s teachings that expression of twist were not observed in colon, ovary and lung cancer it would be unpredictable to use the teachings of the specification to extrapolate to “any” cancer, when the art teaches not all cancers have altered or detectable expression of twist.

Further it would be unpredictable to extrapolate the findings of altered expression in breast cancer or neuroblastoma to "any" subject in view of the teachings of Brenner. Brenner teaches that a gene in two species often have different physiological response as the species have evolved in different environments. It would thus be unpredictable to extrapolate what expression of one gene or homologue in one species to another species without demonstration that the genes have the same function in both species.

Further as the specification teaches the altered regulation of a single twist gene it would be unpredictable to extrapolate these findings to “any” twist gene, splice variant, mutant of any species.

The claims are broadly drawn to the detection of altered gene expression in “any” tissue or blood the specification has provided no evidence that the expression of twist in blood is indicative of altered prognosis or diagnosis of cancer. In view of the teachings

of Rosivatz, Maestro, Fackler and Sukumar that altered expression of twist is not found in the affected tissue it would be unpredictable to associate altered expression in other tissues that are not directly involved. Further as GeneCard teaches twist gene expression is varied across tissues it would be unpredictable to compare expression in any tissue sample.

Further as the specification nor claims teach how the expression levels are normalized it would be unpredictable to associate altered expression of a gene with a disease state without proper controls for normalizing expression as taught by Vandesompele, Cheung, Newton. The cited reference teach that gene expression is variable and without proper normalization controls, there is great variability and unpredictability in expression analysis. Therefore it would have been unpredictable to associate altered expression of twist in any model with diagnosis or prognosis of "any" cancer without specific guidance to what genes are required for normalization.

Therefore, in light of the breadth of the claims, the lack of guidance in the specification, the high level of unpredictability in the associated technology, the nature of the invention, the negative teachings in the art, and the quantity of unpredictable experimentation necessary to practice the claimed invention, it would require undue experimentation to practice the invention as claimed.

3. Claims 3-6 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a method of detecting any gene that can broadly be interpreted as a “twist gene” in any species by the use of "any” twist specific reagent. The claims do not set forth any structural requirements for a twist gene.

When the claims are analyzed in light of the specification, the invention encompasses an enormous number of antibodies, nucleotide molecules, or twist specific reagents. The specification does not teach the sequence of the twist gene, nor any identifying characteristics of twist specific reagents.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been by full structure. The instant specification does not teach a single representative species of a twist gene.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. other nucleotide sequences or positions with in a specific gene or nucleic acid), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case the specification provides no structural limitation or functional limitation for the twist gene. The claims read in light of the specification encompass any nucleic acid molecule that can broadly interpret as a twist gene from any species.

Twist1 GeneCard (GC07M01921, pages 1-13, 5/6/2006) teaches that the recitation of Twist broadly encompasses 52 cDNA and 31 SNPs from humans. Thus

the claims encompassing “any” species encompass an enormous genus of nucleic acids.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

In the instant application, the provided information regarding nucleic acid twist, do not constitute an adequate written description of the broad subject matter of the claims, and so one of skill in the art cannot envision the detailed chemical structure of the nucleic acids encompassed by the claimed nucleic acids. Adequate written description requires more than a statement that nucleic acids with a particular quality are part of the invention and reference to a potential method for their identification. The nucleic acid sequence is required.

In conclusion, the limited information provided regarding twist is not deemed sufficient to reasonably convey to one skilled in the art nucleic acid molecules represented by the recitation of "twist" in any species.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-6 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because the claims do not recite the basic steps of the claimed invention in a positive, active fashion (see Ex parte Erlich 3 USPQ2d, 1011). The claim describes a method for prognosing and/or diagnosing cancer, but the claim fails to recite any actual steps that define the method. The limitation that the procedure "using a biological sample take from a patient, according to which expression of the twist gene is determined" is not considered to meet the requirement of a positive process step because no guidance is given as to how to collect a biological sample, determine expression and diagnose.

Claims 3-6 and 8-11are indefinite because it lacks a positive active step relating back to the preamble. The preamble recites a method of prognosing and/or diagnosing cancer, however the last positive active step is drawn to detecting. Therefore it is unclear as to whether the method is drawn to prognosing and/or diagnosing cancer or prognosing and/or diagnosing cancer.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 3-6 and 8-11are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al (Breast Cancer Research and Treatment (2003) volume 82, supplement 1, pages S117-S118, December 3, 2003).

It is noted that this rejection does not contradict the enablement rejection as it merely demonstrates that the steps of the invention had previous been done. As addressed in the enablement rejection the art has taught the step of detection and the level of expression with breast cancer appears to be unpredictable. The instant rejection is presented to the active step of the claims.

As noted in the MPEP 2111.02, “If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention’s limitations, then the preamble is not considered a limitation and is of no significance to claim construction.” Accordingly, the claim language of "a method of diagnosing and/or prognosing cancer” merely sets forth the intended use or purpose of the claimed methods, but does not limit the scope of the claims.

The claims are drawn to a method of detecting the expression of twist. Claim 4 required providing a sample, a reagent specific for twist and determining the expression of twist.

With regards to claims 3-6, 8-11, Martin et al teach expression of twist was determined in breast cancer and background tissue. Martin teaches twist expression was determined by Q-PCR. Q-PCR is a reagent specific to twist. Martin teaches twist

expression was higher in tumor samples than controls. Thus Martin teaches a method comprising the steps of extracting a biological material from a sample, providing at least one reagent specific for the twist gene, using a tissue sample from a breast cancer patient.

Summary

No claims are allowed.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Sarae Bausch/
Primary Examiner, Art Unit 1634